201-14363

NCIC HPV
Sent by: Mary-Beth Weaver

To: NCIC HPV, moran.matthew@epa.gov
cc:
cc:
Subject: HPV registration number

03/25/2003 12:23 PM

John Heinze <jheinze@johnadams.com> on 03/24/2003 04:42:00 PM

To: Rtk Chem/DC/USEPA/US@EPA, oppt.ncic@epamail.epa.gov
cc: Richard Hefter/DC/USEPA/US@EPA

Subject: HPV registration number

Huntsman LLC (formerly Huntsman Corporation) is hereby submitting a cover letter, revised assessment plan report and robust summary document for Benzene, C6-12 alkyl derivatives, CAS #68608-80-0 under the U.S. Environmental Protection Agency's (EPA) High Production Volume Chemical (HPV) Challenge Program. These revised documents address the comments posted to the HPV web site by EPA and Environmental Defense.

Hard copies of the documents are being mailed to Oscar Hernandez, Ph.D., Director, Risk Assessment Division, who provided EPA's comments.

Huntsman believes that the current revised documents meet the requirements of the voluntary HPV Challenge Program and that additional animal testing would not provide significant new information useful in decision making.

Thank you for review and thoughtful comments. If you have any questions regarding the assessment plan report or the robust summaries, please contact me at 202-737-8400 (telephone), 202-737-8406 (fax) or jheinze@iohnadams.com (email).

Sincerely,

--John E. Heinze, Ph.D.

Senior Vice President, Science

John Adams Associates Inc.

Transmittal Letter.pdf

Revised Final Assessment Plan 3-12-03.pdf

Final Robust Summary Document 2-24-03.pdf

201-14363

John Adams
ASSOCIATES INC.

March 21, 2003

Oscar Hernandez, Ph.D.
Director, Risk Assessment Division
U.S. Environmental Protection Division
Washington, D.C.

Dear Dr. Hernandez:

Huntsman LLC (formerly Huntsman Corporation) is submitting for review a revised assessment plan report and robust summary document for Benzene, C_{6-12} alkyl derivatives, CAS #68608-80-0 under the U.S. Environmental Protection Agency's **(EPA)** High Production Volume Chemical (HPV) Challenge Program. These revised documents address the comments posted to the HPV web site by EPA and Environmental Defense.

An overview of the revisions is presented herein to facilitate further review by **EPA** and other interested parties. Overall, the revisions can be classified into the following groups.

1) Additional information to characterize the chemical composition **of** the sponsored chemical mixture and how the current material relates to the materials tested.
2) Additional clarification of the limited exposure potential of the sponsored chemical.
3) Additional discussion to clarify the results of the biodegradation and other key studies.
4) Provision of additional detail in the robust summaries where available.

Each of these areas is discussed in more detail below. Additional information is provided as needed to address specific comments in the physicochemical properties, environmental fate, ecotoxicity, and toxicity sections of the reports.

Characterization of the Sponsored Chemical

EPA indicated in its comments that additional information was needed to clarify the chemical composition of the sponsored chemical and how the current Alkylate Top relates to the materials tested.

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Founding Partner, The WORLDCOM Group, Inc. with over 100 offices worldwide.

To address this comment and to fully characterize the Alkylate Top material, Huntsman LLC undertook a sampling and analysis program in the fall of 2002. In this program, a total of **21** samples were collected during both light and heavy paraffin campaigns and analyzed by gas chromatography (GC) and gas chromatography-mass spectrometry (GC/MS). These analyses provided the raw data for the relative percent value ranges summarized in Table 1 and the discussion of the revised assessment plan report.

Additional information on the Alkylate Top tested has also been added and discussed further in the robust summaries and assessment plan. Additional information has been added to clarify the relationship of the Alkylate Top with the constituent materials and LAB included in the report.

The additional discussion clarifies the composition of the Alkylate Top and the tested materials and addresses the applicable comments.

Clarification of the Limited Exposure Potential

The revised assessment plan clarifies the limited exposure potential of the sponsored material. Currently, 100% of the Alkylate Top produced is sold into the marine diesel fuel market as a blend stock for viscosity control. Production of the material occurs in a closed process, and standard personal protective equipment is sufficient to minimize exposure. During use, very limited human and environmental exposure is expected, given the small percentage of Alkylate Top present in the marine diesel fuel and its destruction during the combustion process.

Given the very limited exposure potential of the sole use of Alkylate Top, the available data are sufficient to characterize the hazard potential of the sponsored material.

Biodegradation

EPA comments indicated that the data for the biodegradation study conducted on the Alkylate Top may not be adequate because the reported results were for a 35-day study instead of the standard 28-day OECD Guideline 301 study.

Huntsman LLC agrees that the study deviated slightly from the standard OECD protocol and additional information has been added to robust summary to clarify the study design and the relevance of the results. Overall, the study is essentially similar to current OECD protocols and CO_2 evolution was measured at **3,** 7, 14, **2**1, **28** and 3**5** days. While only the **3**5 day mean

CO_2 evolution was reported, the data clearly show that degradation occurred during the study. Given the higher percentage of the less degradable indanes in the tested material as compared to the current Alkylate Top, the test results demonstrate that substantial biodegradation of the Alkylate Top is likely to occur in the environment. Combined with the lack of significant exposure potential, the biodegradation data presented for the Alkylate Top and its constituent and benchmark compounds sufficiently meets the requirements of the HPV Challenge program.

Chronic Aquatic Invertebrate Testing

EPA suggested in its comments the need to conduct a 21-day chronic reproductive study in *Daphnia*. The rationale for this suggestion was the guidance that testing should be conducted on chemicals with log K_{ow} values between 4.2-7.25. Huntsman LLC has reviewed the data available on the constituent materials and LAB and notes that the estimated K_{ow} values are generally high (7.11-9.12), falling at the high end or above the range suggested in the guidance. In addition, the very low water solubility and the limited exposure potential of the Alkylate Top suggests that additional animal testing would not contribute significantly to the decision-making process. Given all of these factors, the available data are considered adequate for the HPV Challenge Program and no chronic daphnid testing is planned at this time.

Provision of Additional Detail in the Robust Summaries

EPA indicated that some of the robust summaries did not provide sufficient details necessary for an independent assessment of their quality. Therefore, Huntsman LLC has again reviewed each of the robust summaries and acquired additional primary literature when it was available. Any additional detail that could be derived from the data sources was added to the robust summaries. Additional information was also added to the assessment plan report where needed to assist in the evaluation of the available data. In some cases, additional information was not available, however the available data are generally quite consistent, which when combined with the overall lack of significant toxicity provides confidence in the observed trends. Additional information specific to each of the data types is outlined below.

Physicochemical ***Properties***

- Huntsman agrees that the physicochemical property data are adequate for the HPV Challenge Program.

Environmental Fate

- The EQC Level III model results using EPI Suite v.3.10 was used to estimate the transport and distribution of the chemicals. Because the Alkylate Top is a mixture, the range of distribution values for each environmental compartment was derived from modeling of the constituent materials and LAB.

Ecotoxicity

- All robust summaries have had additional detail added wherever available.
- The test material composition for the first fish acute summary was clarified.
- The data from two studies reported in one robust summary have been separated into two separate robust summaries according to EPA comments.

Health Effects

- All robust summaries have had additional detail added wherever available.

Summary

Huntsman LLC has provided a revised assessment plan report and robust summaries for Benzene, C_{6-12} alkyl derivatives ("Alkylate Top") under EPA's HPV Challenge Program. Huntsman has made every attempt to address the comments received from EPA and other interested parties in these revised documents.

Huntsman LLC has provided additional information to clarify the chemical composition of the sponsored chemical and show the relationship between the Alkylate Top and the materials tested. Additional information has been provided to further clarify the limited exposure potential of the Alkylate Top and clarify the results of key studies. Additional details have been added to the robust summaries and the assessment report where available. While the quality and availability of the data vary, the data consistently indicate a lack of significant toxicity.

The available data indicate that the sponsored Alkylate Top is of low toxicological concern. Furthermore, its production in closed manufacturing processes and its sole use as a component that is blended into marine diesel fuel significantly limits the human and environmental exposure potential. Therefore, taking all of these factors into consideration,

Huntsman believes that the current revised documents meet the requirements of the voluntary HPV Challenge Program and that additional animal testing would not provide significant new information useful in decision making.

Thank you for review and thoughtful comments. If you have any questions regarding the assessment plan report or the robust summaries, please contact me at 202-737-8400 (telephone), 202-737-8406 (fax) or jheinze@johnadams.com (email).

Sincerely,

John E. Heinze, Ph.D.
Senior Vice President, Science
John Adams Associates Inc.

cc: David J. Kent, The Weinberg Group Inc.
Raymond Papciak, Huntsman LLC
Scott W. Waite, Ph.D., Huntsman LLC
John N. Rapko, Ph.D., for Huntsman LLC